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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,101	02/04/2004	Jacques Seguin	CVALVE.006CP1	6184

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EXAMINER

SCHILLINGER, ANN M

ART UNIT	PAPER NUMBER
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3774

NOTIFICATION DATE	DELIVERY MODE
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09/05/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/772,101	Applicant(s) SEGUIN ET AL.	
	Examiner ANN SCHILLINGER	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 111-149 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 111-149 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 111-149 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The newly added limitations describing the valve assembly as having an axial length that permits the assembly to extend from the cardiac annulus into the ascending aorta is not properly supported by the specification.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: paragraph 0119 should be amended to provide antecedent for the claim terminology describing the valve assembly as having an axial length that permits the assembly to extend from the cardiac annulus into the ascending aorta.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 111-116, 118-124, 127-131, 133-146, 148, and 149 are rejected under 35

U.S.C. 102(e) as being anticipated by Garrison et al. (U.S. Pub. No. 2002/0151970). Garrison et al. discloses the following regarding claim 111: a replacement cardiac valve (6) with a plurality of commissure points (see Figure 10, 32), and a plurality of resilient leaflets (paragraph 0061) (Figure 10). Garrison et al. also discloses a collapsible prosthetic cardiac valve support (8; paragraph 0057), attached to the replacement cardiac valve (please see Figures 20, 25, 26) having a first and a second portion (Attachment A), and a first and a second section. The first section expands to a diameter less than first portion (see Figure 8). The cardiac valve assembly disclosed by Garrison et al. extends from the cardiac annulus into the ascending aorta (please see Figures 20, 25, 26). Please note that functional language is used throughout the claims, and in order to be given patentable weight, a functional recitation must be supported by recitation in the claim of sufficient structure to warrant the presence of the functional language. *In re Fuller*, 1929 C.D. 172; 388 O.G. 279.

Garrison et al. discloses limitations of claims 112, 113, 119, 120, and 149 the radial restraint comprising a wire (see Figure 7; paragraph 0058, lines 10-13).

Garrison et al. discloses the limitations of claims 114 and 115 as shown in Figures 9 and 27-33.

Garrison et al. discloses the limitations of claim 116 in paragraph 0069.

Garrison et al. discloses the anchor of claims 118 and 148 in paragraph 0080.

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Garrison et al. discloses the following regarding claim 121: the prosthetic cardiac valve assembly of Claim 15, wherein at least one portion of the single length of wire has a reduced thickness to decrease the radial expansion force (see Figure 7, where the wire shown is capable of decreasing the radial expansion force). With this claim language, Applicant is not disclosing that the wire's thickness varies within the same length of the wire.

Garrison et al. discloses the limitations of claim 122 in Figure 7 and paragraph 0058.

Garrison et al. discloses the limitations of claim 123 and 139 in paragraph 0080.

Garrison et al. discloses the limitations of claim 124 in paragraph 0069.

Garrison et al. discloses the limitations of claim 127, 133, 138, and 146 in paragraph 0080.

Garrison et al. discloses the limitations of claim 128, 136, 140, and 144 in paragraph 0012.

Garrison et al. discloses the limitations of claim 129, 134, and 141 in paragraph 0069.

For claims 130, 131, 142 Garrison et al. discloses a ring stent (111), see Figure 37.

Garrison et al. discloses the limitations of claim 135 and 143 in paragraphs 0008 and 0009.

Garrison et al. discloses the following regarding claim 137: a replacement cardiac valve assembly (6, 8) with an axial cardiac valve support portion (8) and at least one leaflet. The support portion has a second section, and at least one radial restraint (see Figure 7; paragraph 0058, lines 10-13) at a first section (see Attachment A). Please also see paragraphs 0058-0080. The cardiac valve assembly disclosed by Garrison et al. would be able to extend from the cardiac annulus into the ascending aorta (please see Figures 20, 25, 26; paragraph 0069).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 117 is rejected under 35 U.S.C. 103(a) as being unpatentable over Garrison et al. et al. in view of Schwartz et al. (US Pub. No. 2002/0099439). Garrison et al. discloses the claimed invention except for a drug-eluting component that is included with the valve. Schwartz et al. teaches including such a compound with the valve to prevent cell overgrowth or extracellular matrix production in the same field of endeavor (paragraphs 0014, 0023, 0083). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to include these drug-eluting compounds with the valve to prevent cell overgrowth or extracellular matrix production.

Claim 125 is rejected under 35 U.S.C. 103(a) as being unpatentable over Garrison et al. in view of Kocur (US Patent No. 6,350,277). Garrison et al. does not disclose the use of a shape memory material. However, Kocur teaches the use of nitinol in a stent (col. 6, lines 36-39) that will assist the prosthetic valve to better fit in the area where it is replacing the deficient native valve. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a shape memory material such as nitinol to assist the prosthetic valve to better fit in the area where it is replacing the deficient native valve.

Claim 126 is rejected under 35 U.S.C. 103(a) as being unpatentable over Garrison et al. in view of Shaolian et al. (US Patent No. 6,299,637). Garrison et al. does not disclose the use of

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a cuff constraint component. Shaolian et al. teaches the use of a cuff in the same field of endeavor in elements 50, 52, 54; col. 6, lines 30 through col. 7, lines 5 for the purpose of providing radial support. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use cuff constraint component in order to provide radial support.

Claims 132 and 147 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garrison et al. in view of Kocur (US Patent No. 6,350,277). Garrison et al. discloses the use of a stent with the valve system, but does not disclose all of the specific features of the stent as described by the applicant. Kocur discloses the valve assembly further composing a stent configured to reduce the recoil of the support portion following self-expansion of the support portion (col. 3, lines 16-26). And Kocur discloses the valve assembly wherein the stent is configured to reside outside the valve support portion when deployed (col. 6, lines 56-60). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a stent configured to these specifications to allow the stent to work more efficiently with the prosthetic valve system.

Response to Arguments

In view of the amendments submitted on 5/1/2008, the 35 U.S.C. 112, second paragraph rejection is withdrawn.

The Applicant contends that the Garrison et al. reference does not have an axial length that permits the replacement valve assembly to extend from the cardiac annulus to the ascending aorta. However, Garrison et al. shows in Figures 20, 25, and 26 that the valve assembly extends from the cardiac annulus into the ascending aorta, thus meeting the claims' limitations.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN SCHILLINGER whose telephone number is (571)272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571) 272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. S./
Examiner, Art Unit 3774

/William H. Matthews/
Primary Examiner, AU 3774

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Attachment A

